

## **REMARKS**

Applicant has carefully reviewed the Final Office Action mailed December 22, 2003 regarding the above-referenced patent application. Currently claims 1, 2, 5-8, 15-18, 22 and 24 are pending in the application, and claims 1, 2, 5-8, 15-18, 22 and 24 have been rejected. Consideration of the following remarks in view of the current claims as reproduced above is respectfully requested.

### **Information Disclosure Statement**

In response to the request from the Examiner, Applicant is submitting a copy of the IDS and accompanying references originally submitted December 25, 2002. As the IDS and references were timely submitted, as indicated by the stamped postcard, a copy of which is included, Applicant requests consideration of the references.

### **Claim Rejections—35 U.S.C. § 102**

Claims 1, 2, 5-8, 15 and 16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Yoon et al. (U.S. Patent No. 5,800,394). Applicant respectfully traverses this rejection.

Yoon et al. fail to teach each and every element of the invention of claim 1. Specifically, claim 1 recites “an expandable chute disposed upon, and in fluid communication with, the distal end of the cannula, the chute expanding radially from a contracted configuration to an expanded *conical* configuration when in use” (emphasis added). Yoon et al. only disclose an expandable membrane which has “a predetermined or preformed triangular configuration in side view in the expanded position”. Column 5, lines 44-45. That this triangular configuration in side view is not a conical configuration is made clear by the next few lines: “The expandable member 16 can have various configurations in end view as disclosed in prior application Ser. No. 08/249,116.” Column 5, lines 46-48. This application has issued as Pat. No. 5,514,091 to Yoon. Figures 29A-29E of this patent disclose the various end view configurations, all of which are long and narrow. Therefore, Yoon et al. disclose no chutes having an expandable conical configuration.

By having a chute with an expanded conical configuration, the claimed invention has several advantages. For example, since the expanded conical chute is symmetrical about the longitudinal axis, the operator need not worry about proper axial orientation of the instrument.

In contrast, with a triangular configuration, there may be no ready way to determine the axial orientation without at least a partial expansion. Rotating the instrument when expanded is probably not feasible without trauma to the surrounding tissue. In another example advantage, the expanded conical configuration when used to pull back the papilla tissue applies a more uniform pressure on the tissue than a triangular shaped apparatus would. This likely results in less irritation or trauma to the tissue.

Applicant, therefore, believes that claim 1 is in condition for allowance. As claims 2, 5-8, 15 and 16 depend from claim 1 and contain additional features, applicants submit that these claims are in condition for allowance as well.

### **Claim Rejections—35 U.S.C. § 103**

Claims 17, 18, 22 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoon et al. in view of Karpiel (U.S. Patent No. 5,320,602). Applicant respectfully traverses this rejection.

Yoon et al. teach an expandable instrument for creating a space at an obstructed site in the body by expanding a distal part of the instrument to force tissue aside. Karpiel teaches a peel-away endoscopic retrograde cholangio pancreatography catheter, the use of which is intended to be asatraumatic as practicable.

Applicant submits that no prima facie case of obviousness has been made because there is no motivation or suggestion for one of ordinary skill in the art to modify Yoon et al. in view of Karpiel. The Examiner suggests that the motivation may be to modify Yoon et al. by adding a tapered tip from Karpiel to the outer tubular member so that the device has a less obtrusive profile. This, however, would make the device of Yoon et al. unsatisfactory for its intended purpose of displacing obstructed tissue. If the device of Yoon et al. is used by itself, the tip needs to be obtrusive to force its way through tissue to the treatment site. If the device is inserted through a separate catheter, whether the tip is tapered or not is irrelevant because the limiting factor is the overall size of the outer tubular member. No advantage would be gained from a tapered tip in this situation.

As no prima facie case of obviousness has been established, Applicant requests withdrawal of the rejection and submits that claim 17 is in condition for allowance. As claims

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· Resp. AF dated February 11, 2004  
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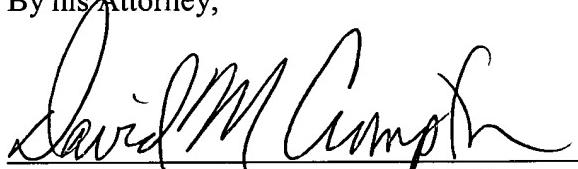
18, 22 and 24 depend from claim 17 and contain additional elements, Applicant submits that these claims are also in condition for allowance.

Reexamination and reconsideration of all pending claims, namely claims 1, 2, 5-8, 15-18, 22 and 24, is respectfully requested. It is believed that all pending claims are in condition for allowance, and issuance of a Notice of Allowance in due course is respectfully requested. If a telephone conference may be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,



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